

ATTACHMENT A

FILED
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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MONTANA

MISSOULA DIVISION

UNITED STATES OF AMERICA)
Plaintiff,) Cause No.: CR-05-07-M-DWM
v.)
W. R. GRACE, ALAN R. STRINGER,) DEFENDANTS' JOINT MOTION IN
HENRY A. ESCHENBACH, JACK W.) LIMINE TO EXCLUDE EXPERT
WOLTER, WILLIAM J. McCaig,) EVIDENCE RELATING TO THE ATSDR
ROBERT J. BETTACCHI, O. MARIO) MEDICAL TESTING PROGRAM AND
FAVORITO, ROBERT C. WALSH,) MEMORANDUM OF LAW IN SUPPORT
Defendants.) THEREOF
EVIDENTIARY HEARING REQUESTED

In 1999, the Federal Government conducted a screening program in Libby, Montana to identify "potential" asbestos exposure pathways in Libby that should be investigated further. This effort became known as the ATSDR Screening Program. Despite its limited goals, it has become a centerpiece of the Government prosecution and the swirl of media accusations concerning W.R. Grace and the town of Libby. This motion is the beginning of the Defendants'

attempt to bring to light the facts and science, devoid of emotion and hyperbole, concerning asbestos disease in the town of Libby, and the ATSDR Screening Program.¹

To begin, there are two fundamental facts about the Screening Program that *are not in dispute*: First, the Screening Program was not designed to establish, and does not support, a *causal* relationship between any of the exposure pathways identified in the Screening Program, and pleural abnormalities. Second, the Screening Program was not designed to determine whether the pleural changes were *caused by asbestos*. Rather, the individuals with pleural abnormalities identified in the screening were simply referred for further examination and a determination of whether or not the individuals had an asbestos-related disease, a smoking-related disease, an obesity-related disease, or, perhaps, no disease at all.

Although the ATSDR Screening Program was designed only as a "screening"—intended to provide information useful for follow-up investigations -- it now lies at the heart of the Government's contention in the Indictment that tremolite from the Libby mine has *caused* asbestos disease in over 1,200 residents in Libby, and it provides the basis for the allegation that environmental asbestos exposures *caused* disease in the population. The ATSDR investigation never was intended to support such far-reaching propositions, and reliance upon it for such propositions, by the Government and its experts, is misleading, and precisely the type of unreliable testimony that should be excluded under Rule 702, *Daubert*, its progeny and Rule 403.

In this criminal prosecution, the question of causation is front and center. "Releases" into ambient air cannot be found to have "endangered" anyone unless the Government can

¹ The Defendants, through counsel for Grace, have contacted the Government prior to filing this motion pursuant to Local Criminal Rule 12.2. The Government has indicated that it will object to this motion. In accordance with Local Rule 11.2(b), all parties whose signature lines appear in this motion have consented to and join in its filing.

demonstrate that those releases cause a substantial risk of serious harm to human beings. The ATSDR did not find such a causal relationship. At most, it found that it is *possible* that certain exposure pathways could lead to asbestos-related disease. "Possibility" in science is merely a hypothesis that requires testing. The law does not permit criminal conviction on untested hypotheses. In this case, the Government would like its experts to be able to tell the jury that the ATSDR Screening Program found that environmental exposure from the Libby mine "possibly" caused disease in over 1200 people. Particularly when presented by experts, this is precisely the kind of evidence that causes juries to convict for the wrong reasons. The problems caused by the scientific uncertainty in the Screening Program are compounded by the problems that arise from the fact that the ATSDR Screening Program investigated only exposures in Libby *prior to 1991*. And, given the latency of asbestos-related disease, most of the exposures at issue actually would have occurred prior to 1980 or before.

Finally, but critically, the Government wants to be able to tell the jury that over 1,200 people have been found to have asbestos disease and that many of these diseases were caused by environmental contamination from the Libby mine; yet, remarkably, the Government has not provided the underlying ATSDR x-rays and CT scans to the Defendants during discovery, the very data that would allow the Defendants to test this assertion. Because the Defendants have not had opportunity to review and test the underlying medical evidence, the Government cannot be permitted to introduce this evidence at trial.

BACKGROUND

The ATSDR itself has stated *unequivocally* that the Screening Program *was not designed* to determine whether or not there is a causal relationship between environmental asbestos exposure and risk of asbestos disease, nor is the Screening Program *capable* of rendering evidence to support such an opinion:

- “The program was not designed as an analytic epidemiologic study with comparison groups and random sampling of exposed and comparison groups.” August 23, 2001 *Year 2000 Medical Testing of Individuals Potentially Exposed to Asbestiform Minerals Associated with Vermiculite in Libby Montana: A Report to the Community*, at 1. Exh. 1; *see also 2001 Preliminary Findings of Medical Testing of Individuals Potentially Exposed to Asbestiform Minerals Associated with Vermiculite in Libby Montana: An Interim Report for Community Health Planning*, at 9, Exh. 2 (same).
- Dr. Lybarger, who was one of the primary authors of the ATSDR Screening Program, explained to members of Congress that “the medical testing program does not constitute a ‘study’ because there is no control population, which presents some limitations in interpreting the data.” (Minutes of Lybarger briefing to Congressional delegation, AJL1006258), Exh. 3.
- In the ATSDR’s response to public comments, it further confirmed that “the purpose of this information is to characterize possible pathways of exposure in the community that EPA needs to evaluate. It is not being collected to attribute causality to asbestos contaminated vermiculite on an individual nor population basis. This medical testing program is not a study.” (ATSDR Response to Comments, AJL1013069), Exh. 4.

Rather, the ATSDR Screening Program was designed for different purposes. The main objectives of the ATSDR Screening Program were to *a*) identify and quantify *possible* asbestos-related pleural and interstitial abnormalities among participants and *b*) examine *associations* between these outcomes and the participants’ exposure histories.” Peipins, et al, *Radiographic Abnormalities and Exposure to Asbestos-Contaminated Vermiculite in the Community of Libby Montana, USA*, Env. Health Perspectives, November 2003, 111:1753 at 1754 (emphasis added), Exh. 5. Indeed, in this criminal prosecution, the Government’s experts do not contend otherwise. Dr. Lockey, one of the Government’s experts, candidly admits that the ATSDR Screening Program does not provide a scientific basis for a causal inference about asbestos exposure in Libby and asbestos-related disease. *See* Lockey Disclosure at 13, (“As stated in the report, the program was not designed to be an analytic epidemiologic study, but more of a medical testing or screening”). Further, the exposures that were studied all occurred prior to 1991. *See* Peipins at 1754 (“People were eligible for participation in the medical testing program if they resided, worked attended school, or participated in other activities in the Libby, Montana area for [greater

than or equal to] 6 months before 31 December 1990."); *see also* Lybarger Physician Results Letter, EAM2004206, Exh. 6 ("This LCEHP medical testing was designed to screen individuals who lived, worked or played in Libby, Montana at least 6 months prior to December 31, 1990 . . ."). Indeed, most of the relevant exposures appear to have occurred well before 1990. *See* Price Disclosure, at 26. And finally, there has never been an attempt, let alone a scientifically reliable analysis, by the Government or any of its experts, to establish that the exposures studied in the ATSDR Screening Program are similar in any way to any of the alleged releases in the Indictment, let alone to the alleged ambient air releases in Libby post-1999.

Even with respect to the purposes for which it was designed, however, the ATSDR recognized that the Screening Program suffered from important limitations with respect to its ability even to identify the existence or "*occurrence*" of asbestos-related disease in the individuals who were screened. First, as the Government's own expert, Dr. Lockey, acknowledges, the screening was only intended to identify "potential" pulmonary abnormalities. *See* Lockey Disclosure at 13. According to Dr. Lockey, "[u]nder *some* circumstances the results of the medical tests provide enough definitive information to establish a diagnosis. In *other* cases, additional diagnostic tests may have been indicated before a definitive diagnosis could be derived." *Id.* (emphasis added). Indeed, the letters sent to individuals screened by the ATSDR indicate that *none* of the screenings were, or were intended as a diagnosis of an asbestos-related disease. *See* ATSDR Respondent Results Letter, EAM2004197, Exh. 7.

To compound problems even further, the ATSDR departed from medically-accepted methodology for conducting a medical screening. According to the ATSDR, the investigators reading x-rays were not blinded, as required by the well-established International Labor Organization Guidelines. *See* Peipins, at 1758; International Labour Office, *GUIDELINES FOR*

THE USE OF THE ILO INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSIS ("ILO Guidelines") Geneva, 2000, at 5, Exh. 8. The ATSDR also failed to include control films during the Screening Program, which, as observed by the ILO, allows for assessment of inter- and intra-reader variability; and the ATSDR included oblique films which should not be evaluated in this type of screening.

By the Government's own admissions then, the Screening Program does not render any diagnosis of asbestos-related disease, does not permit causal inferences about environmental asbestos exposure in Libby and asbestos disease, and certainly provides no evidence concerning endangerment in the post-1999 period. Despite this, the Government saw fit to include wildly inappropriate and unsupportable statements about the results of the ATSDR Screening Program in the Indictment, which have been repeated incessantly in the media. See Indictment at ¶ 57 ("To date, approximately 1,200 residents of the Libby, Montana area have been identified as having asbestos related pleural abnormalities as a result of being exposed to tremolite asbestos"); *see also W.R. Grace Indicted Over Asbestos Claims*, CNN Online, February 7, 2005 (http://money.cnn.com/2005/02/07/news/midcaps/wr_grace/), Exh. 9. And now the Government seeks to perpetuate this misuse of science in this criminal prosecution. In a criminal trial, however, scientific testimony and evidence must be based upon reliable scientific data and methods, and the opinions expressed must be relevant to the issues in the case. The ATSDR Screening Program does not provide reliable evidence capable of assisting the jury with any issue in dispute in the criminal prosecution, and indeed, admission of any such evidence clearly will confuse the issues and make it likely that the jury will convict the Defendants on an improper basis.

ARGUMENT

- I. EXPERT EVIDENCE REGARDING THE ATSDR SCREENING PROGRAM DOES NOT FIT THE CASE AND WILL NOT ASSIST THE TRIER OF FACT BECAUSE THE SCREENING PROGRAM DOES NOT PROVIDE INFORMATION ABOUT ENDANGERMENT RESULTING FROM RELEASES THAT ARE RELEVANT TO OR SIMILAR TO RELEASES DESCRIBED IN THE INDICTMENT**

In elucidating the requirement of relevance in the context of expert testimony, the Supreme Court noted that scientific expert testimony must "fit," that is, be relevant to, the allegations that the testimony is seeking to support. "Federal judges must therefore exclude proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to an issue in dispute in the case, and that it will not mislead the jury." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995); *United States v. Hankey*, 203 F.3d 1160 (9th Cir. 2000).

The Government's experts propose to offer expert testimony of an association or correlation between asbestos disease and certain alleged environmental exposure pathways in Libby. Lockey Disclosure, at 16-17; Peronard Disclosure at 14. However, according to the ATSDR itself and the Governments' experts, the ATSDR Screening Program tested only individuals who had resided, worked, attended school or participated in other activities in the Libby, Montana area for at least six months *prior* to December 31, 1990. Peipins at 1754. Indeed, in the Questionnaire itself, participants are instructed only to report exposures that occurred prior to that time period. See Libby Community Environmental Health Program Census Questionnaire, NORC1000045, Exh. 10. This is consistent with the concept of latency and the study of asbestos-related conditions.

In light of this, the only possible relevance the Screening Program could have to the exposures in the Indictment would be if the Government somehow could demonstrate, through a

reliable scientific method, that the exposures examined in the Screening Program, were substantially similar to the levels and kind of releases alleged in the indictment. However, neither the Government nor its experts have made such an attempt - nor could they. Neither the Government nor its experts have identified a scientifically reliable connection between the exposure pathways identified in the Screening Program, and the "releases" alleged in the indictment. There is no quantification of exposures in the ATSDR study, nor is there any description of the particular circumstances of the exposures in the Program. Indeed, there is not even an identification of the date or time period of the alleged exposures, except that they all are supposed to have occurred prior to 1991. Indeed, we know that some of the exposures occurred prior to 1963 before Grace even bought the mine. Price Disclosure at 13-14.

Even if the Government experts were to now attempt to "say" or "opine" that the exposures are substantially similar to releases alleged in the Indictment, that would not be sufficient because Rule 702 requires a scientifically reliable method connecting the exposures studied in the Screening Program, and the releases alleged in the Indictment, whether post-1999 or pre-1999, or pre-1990. Under *Daubert*, the opinion not only has to fit the case, but it has to "fit" the data supporting the opinion. *Daubert II*, 43 F.3d at 1315. Accordingly,

[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to the existing data only because by the underlying *ipse dixit* of the expert. A court may conclude that this is simply too great an analytical gap between the data and the opinions proffered.

Id. Despite these well-established requirements, the Government's experts have offered *no evidence* attempting to connect the pre-1990 environmental exposures identified in the ATSDR Screening Program to ambient air exposures relevant to the post-1999 releases identified in the Indictment, or to any other releases alleged in the Indictment. Thus, any expert opinions relating to endangerment that are based upon the ATSDR Screening Program must be excluded because

there is "too great an analytical gap between the data, and the opinions offered." *See Schudel v. Gen. Elec. Co.*, 120 F.3d 991, 997 (9th Cir. 1997) (expert testimony excluded where no evidence that exposure at issue was substantially similar to exposures examined in studies relied upon by expert); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Domingo v. T.K.*, 289 F.3d 600 (9th Cir. 2002) (expert's opinion did not provide necessary link to opinion regarding the specific disease at issue); *Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1132 (D. Ariz. 2001) (expert's conclusions that exposure caused harm excluded because it was based on too great a "jump" from the cited literature); *Carnegie Mellon Univ. v. Hoffman LaRoche, Inc.*, 55 F. Supp. 2d 1024 (N.D. Cal. 1999) (expert testimony excluded because conclusion involved too great an analytical gap).²

II. THE ATSDR SCREENING PROGRAM IS INADMISSIBLE TO ESTABLISH A CAUSAL LINK BETWEEN EXPOSURE PATHWAYS AND RADIOGRAPHIC CHANGES RELATED TO ASBESTOS AND, AS SUCH, IS NOT RELIABLE SCIENTIFIC EVIDENCE UNDER DAUBERT

"Epidemiological studies examine the pattern of disease in human populations." *Joiner*, 522 U.S. at 144 n.2. Epidemiological studies are particularly valuable in showing causation when toxic substances are alleged to cause disease or risk of disease. *See Moolgavkar Disclosure* at 3; *see also Brock v. Merrell Dow Pharm. Inc.*, 874 F.2d 307, 315 (5th Cir. 1989) (finding that epidemiological studies are, "[u]ndoubtedly, the most useful and conclusive type of evidence" in cases involving toxicity and disease); *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1356 (N.D. Ga. 2001) ("[E]pidemiological studies provide 'the primary generally

² Even if the Courts finds that the analytical gap between the ATSDR releases and the releases relevant in the Indictment is not sufficient, alone, to exclude the data, the Court should exclude it still because any probative value is outweighed by the danger of prejudice and confusion. *See infra* Section IV.

accepted methodology for demonstrating a causal relationship between a chemical compound and set of symptoms or disease."); *Lynch v. Merrell-National Labs.*, 646 F. Supp. 856 (D. Mass. 1986), *aff'd* 830 F.2d 1190 (1st Cir. 1987). The ATSDR Screening Program did not adhere to proper scientific methodology for determining disease causation, and therefore, it is not reliable and it does not provide information that supports an expert opinion that would be helpful to the trier of fact.

A. The ATSDR Screening Program Lacks The Fundamental Features Of An Epidemiological Study - Such As A Control Group And Random Sampling - That Can Be Used To Infer Causation.

The ATSDR Screening Program did not follow established epidemiologic methodology because it did not use a control group. *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("[C]ase reports are not reliable scientific evidence of causation, because they simply described reported phenomena without comparison to the rate at which the phenomena occur in the general population or control group; do not isolate or exclude potentially alternative causes; and do not investigate or explain the mechanism of causation."); *Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1161-62 (E.D. La. 1997) ("courts have frequently rejected case studies as an insufficient basis to decide causation when they lack control groups"). This fundamental and critical fact is *not* in dispute. *See, e.g.*, Exh. 2 at 9; Exh. 1 at 1 ("The program was not designed as an analytic epidemiologic study with comparison groups and random sampling of exposed and comparison groups."); Peipins at 1758 (screened population identified as "no apparent exposure" to Libby asbestos "was based on negative responses to specific pathway questions and is likely to have missed some potential exposure pathways.").

Second, the Screening Program was not based on a random sample and its findings are subject to serious selection bias. Proper epidemiological studies establish protocols that ensure that the study will include a random and representative sample of the larger population at issue if

the study will serve as the basis for an extrapolation of the study's findings to a broader population. *Ratanasen v. Cal. Dep't of Health Servs.*, 11 F.3d 1467, 1472 (9th Cir. 1993) (upholding a finding that a random sampling was "appropriate, valid, and reliable"); *see In re TMI Litig.*, 193 F.3d 613, 708 (3d Cir. 1999) (excluding epidemiological study where participants in the study groups were chosen by plaintiffs' consultant and there was no attempt to insure that participants were not selected or excluded in a manner that would bias the study). The purpose of the random sampling is to ensure that the results may be extrapolated to a larger population with some assurance that the results will be somewhat representative.

The ATSDR Screening Program did not even attempt to study a random sample of the population. In fact, the ATSDR acknowledged that there may have been selection bias that affected the sample of screened individuals. *See Peipins* at 1754, 1758. The ATSDR advertised in the newspapers and elsewhere, encouraging people who thought they might have been exposed to asbestos in Libby to get screened. *Id.* Not surprisingly, the ATSDR observed that "persons who believed they have little or no exposure may have chosen not to participate, or those already diagnosed with disease may have felt that they had little to gain from participating." *Id.* By its own admission, then, the study population likely excluded individuals with no exposure pathways or disease, thus making a comparison to a "non-exposed" population virtually impossible. *Id.* As a result, it is not reliable as an epidemiological study, nor are the Government's experts' opinions comparing results of the ATSDR Screening Program to other populations. Specifically, it is not appropriate for an expert to opine that the number of pleural abnormalities observed in this self-selected group is high compared to the incidence of pleural abnormalities identified in a different randomly selected population.

Moreover, both Dr. Lybarger, a principle investigator for the ATSDR, and Dr. Lockey admit that the ATSDR Screening Program is not an epidemiological study that provides information about causation and disease. *See infra* at 5-6. Nevertheless, both Lockey's and Peronard's disclosures indicate that they intend to offer opinions, based upon the ATSDR Screening Program, comparing the occurrence of pleural abnormalities in Libby to other populations. Lockey Disclosure at 17-18; Peronard Disclosure at 14. Such comparisons are improper and unreliable where, as here, the sampled population has not been randomly selected.

Courts recognize that properly structured epidemiology studies are the proper basis to make statements about causal influence. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 635 (1973); *see also* Moolgavkar Disclosure at 3-4; *Brock v. Merrell Dow Pharm., Inc.*, 874 F.2d 307, 311 (5th Cir. 1989) ("Epidemiology attempts to define a relationship between a disease and a factor suspected of causing it. To define that relationship, the epidemiologist examines the general population, comparing the incidence of the disease among those people exposed to the factor in question to those not exposed."). The Screening Program bears neither of the most important indicia of a proper epidemiological study. As such, it cannot provide the basis for any opinions relating to causation; and thus it may not be relied upon in testimony submitted to the jury for the purpose of inferring causation, including comparisons between the results of this screening and those in other populations. *Fed R. Ev. 702; Daubert v. Merril Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993); *Diviero v. Uniroyal Goodrich Tire Co.*, 114 F.3d 851, 853 (D. Ariz. 1997).

B. The Expert Evidence Relating to the ATSDR Screening Program Does Not Fit Because It Does Not Assist in a Determination About Whether the Exposure Pathways Caused "Risk" or "Endangerment"

There is no dispute that the ATSDR Screening Program is not an epidemiological study and does not establish that exposure to vermiculite through the pathways studied caused asbestos

disease in the Libby population, and the Government's experts have conceded as much. Accordingly, when discussing the findings of the Screening Program in their expert disclosures, the Government's experts couch their opinions in terms of "associations", "relationships", or "potential" when describing the alleged connection between the exposure pathways studied and the alleged abnormalities found. *See, e.g.*, Lockey Disclosure at 13-14, 16. In a nutshell, the Government's experts opine that the ATSDR Screening Program finds a *relationship* between some of the pathways studied and pleural abnormalities, but they appear to concede that the relationship identified has not been found to be a causal relationship. *See* Lockey Disclosure at 13, 16 and 17.

The experts' failure to address causation, however, presents a threshold problem because, in the absence of a causal connection, their opinions do not "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. The Government has claimed that the Defendants caused "imminent risk of serious bodily harm" and that the Defendants' conduct "endangered" the Libby population. Consequently, to the extent the Government's experts fail to state that the exposure pathways studied in the ATSDR Screening Program "caused" the diseases allegedly described, their testimony is not relevant and fails to fit the issues before the jury. *See Daubert*, 509 U.S. at 591 (consideration of "fit" requires that the experts' opinions be sufficiently tied to the facts of the case that it will aid the trier of fact in resolving a factual dispute); *see also Allen v. Penn. Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) ("While appellants' experts acknowledge the lack of statistically significant epidemiological evidence, they rely on certain studies as suggestive of a link between CTO exposure and brain cancer. 'Suggestiveness' is not . . . statistical significance nor did the appellants' experts show why and how mere 'suggestiveness' scientifically supports a causal connection."); *Bradley v. Brown*, 852

F. Supp. 690, 700 (N.D. Ind. 1994) (noting that court “must weed out the speculative hypothesis from tested theory” and rejecting an expert’s conjecture that had “not progressed from the plausible, that is hypothetical, to knowledge capable of assisting a fact finder”). Here, the ATSDR itself has stated publicly:

The purpose of this information [ATSDR Screening Program] is to characterize possible pathways of exposure in the community that EPA needs to evaluate. It is not being collected to attribute causality to asbestos contaminated vermiculite on an individual nor population basis. This medical testing program is not a study.

ATSDR Response to Comments, AJL1013069.

In light of this concession by the Federal Agency that conducted the screening program, the Government, through its experts, should not be permitted to describe the results of this Screening Program, absent a causal finding, because the results of the Screening Program cannot assist the trier of fact in determining a fact in issue – such as endangerment or risk from environmental exposures. The ATSDR Screening Program identifies 1,200 people with *possible* asbestos-related pleural abnormalities. The results of the Screening Program, particularly if provided through the testimony of an expert with an aura of authority, are very likely to confuse the issues and lead the jury to believe, mistakenly, that there has been a scientifically reliable finding of a causal relationship between the environmental exposure pathways studied and asbestos disease in 1,200 individuals in the town of Libby. This is precisely the kind of expert testimony that the Supreme Court recognized should be excluded because its relative probative value is outweighed by the confusion it likely will cause:

In elucidating the fit requirement, the Supreme Court noted that scientific expert testimony carries special dangers to the fact-finding process because it can be both powerful and quite misleading because of the difficulty in evaluating it. *Id.* at 2798 (quoting *Weinstein*, Rule 702 of the F.R.E., 138 F.R.D. 631, 632 (1991). Federal judges must therefore exclude proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to an issue in dispute in the case, and that it will not mislead the jury.

See Daubert II, 43 F.3d at 132 n.17; *see also Mukhtar v. Cal. State Univ.*, 299 F.3d 1053, 1063-64 (9th Cir. 2002) (aura of authority experts exude can lead juries to give undue weight to their testimony).

In sum, the ATSDR does not employ a scientifically reliable methodology that supports expert testimony ascribing a causal relationship between environmental asbestos exposure in Libby and asbestos-related disease. As such, there should be no expert testimony relating to the ATSDR Screening Program because it cannot assist the trier of fact.

III. THE SCREENING PROGRAM'S FLAWS PRECLUDE ITS ADMISSION, UNDER DAUBERT, FOR ANY PURPOSE, BECAUSE THE RESEARCHERS CONDUCTING THE SCREENING PROGRAM DID NOT FOLLOW ACCEPTED METHODOLOGY FOR CLASSIFYING X-RAYS

Rule 702 and *Daubert* require that the methodology used to achieve the result of the underlying study or test be sound. *Kumho Tire v. Carmichael*, 526 U.S. 137, 153 (1999). The ATSDR Screening Program is fundamentally flawed, even for the purposes for which it was intended -- as a screening -- because the B-readers, the individuals who read the x-rays for ATSDR, did not follow the well-accepted methodology promulgated by the International Labour Office for classifying x-rays as part of an epidemiological or screening program.

The International Labour Organization establishes clear guidelines for reading x-rays as part of an epidemiologic study. The ILO Guidelines are "used internationally for epidemiological research, for screening and surveillance of those in dusty occupations, and for clinical purposes." ILO Guidelines at 1. NIOSH, the National Institute for Occupational Safety and Health, acknowledges that "[t]here is a long and distinguished history of using the ILO classification to derive classifications for input to epidemiologic studies . . .). *See* NIOSH, <http://www.cdc.gov/niosh/topics/chestradiography/epidemiologic-research.html>. Use of ILO Guidelines has been recognized time and again by the federal courts as authoritative. *See, e.g.*,

In re Nat'l Gypsum Co., 257 B.R. 184, 233-35 (N.D. Tex. 2000) (in order to recover from the settlement trust, claimants must demonstrate impairment through the use of diagnostic tests, including ILO); *In re Asbestos II*, 142 F.R.D. 152, 156 (N.D. Ill. 1991) (approving ILO criteria in determining seriousness of asbestosis cases); *In re Joint E. & S. Dists. Asbestos Litig.*, 120 B.R. 648, 671 (E. & S.D.N.Y. 1990) (utilizing ILO criteria). Despite this undisputed acceptance within the medical community, the ATSDR departed from the ILO Guidelines in several ways that compromise the ATSDR Screening Program's reliability, even as a screening program.

First, the ATSDR failed to use control films that could have identified any potential bias amongst the readers. Control films are films with known degrees of pleural or parenchymal changes that are used to determine whether the B-readers are accurately reading the x-rays. If the B-readers over-read the control films (*i.e.*, see a greater degree of radiographic changes than actually exists on the film), then this is strong evidence that the B-readers were also over-reading the subject x-rays as well. *See* May 30, 2006 affidavit of Dr. David Weill at ¶ 9, Exh. 11. The use of control films permits the identification of intra and inter reader variability, which can be used to determine whether there is over-reading tendency by a given reader. *Id.* Despite the ease with which it could have included control films, the ATSDR did not use any control films, making it impossible to determine whether the B-readers were over-reading x-rays from Libby.

Id.

Additionally, the B-readers were not "blinded" because they knew they were reviewing films from Libby, Montana, which all three B-readers knew would have a higher incidence of pleural and/or parenchymal changes than a population without any occupational exposure to asbestos. The ILO Guidelines require B-readers to blind themselves to the particulars of a patient when reading films. ILO Guidelines at 12 ("When classifying radiographs for

epidemiological purposes, it is essential that the reader does not consider any other information about the individuals being studied. Awareness of supplementary details specific to individuals can introduce bias into results."); Weill Aff. at ¶ 10. The ATSDR acknowledged that the B-readers knew these were films from Libby, Montana, which created bias. *See* Peipins at 1758 ("Another potential limitation in this analysis was that the B-readers knew that the radiographs were from the Libby medical screening program . . .").

Finally, the ILO "is designed for classifying only the appearances seen on postero-anterior chest radiographs." ILO Guidelines at 12. The ATSDR B-readers, however, read both the P-A x-ray views as well as the oblique x-rays views, which, as the ATSDR acknowledges, will result in a higher sensitivity for identifying pleural changes. Peipins at 1754. This disregard for the ILO Guidelines ensured that the ATSDR Screening Program would find a higher rate of pleural changes than would be identified in an epidemiological study that complied with the ILO Guidelines. *See* Weill Aff. at ¶ 11.

An appropriate methodology is as important to a reliable outcome as is a qualified expert. *Kumho Tire*, 526 U.S. at 153. In the case of the ATSDR Screening Program, the study design ignored settled scientific standards, inexplicably cut corners that would otherwise have increased reliability, and failed to use the level of rigor that a reliable study should be able to boast. *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003) (expert testimony excluded as unreliable where expert failed to perform differential diagnosis required by proper methodology); *Valentine v. Pioneer Chlor Alkali Co.*, 921 F. Supp. 666, 678 (D. Nev. 1996) (expert's opinions excluded because study failed to employ proper and accepted methodology for conducting study).

The importance of following appropriate methodology is particularly critical when it comes to x-ray screenings using the ILO classification system. Following the ILO Guidelines is critical to ensure that the chest radiographs are read in a reliable manner. *See Weill Aff.* at ¶ 13 (“Failure to follow these ILO Guidelines can result in unreliable chest radiograph interpretations.”). The very measures the ATSDR Screening Program failed to employ – such as the use of control films – are the very measures intended to act as safeguards against the over-reading that has been such a recognized problem. *See Id.* These methodological flaws render the Screening Program unreliable under Rule 702 of the Fed. R. Ev., *Daubert* and its progeny.

IV. RESULTS OF THE ATSDR SCREENING PROGRAM SHOULD BE EXCLUDED UNDER 403 BECAUSE IT IS MORE PREJUDICIAL AND CONFUSING THAN PROBATIVE

Federal Rule of Evidence 403 provides that, even if evidence is relevant, it may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. The Advisory Committee Note to Rule 403 explains that “unfair prejudice means an undue tendency to suggest decision on an improper basis.” Advisory Committee Note to Rule 403. In the criminal context, the Supreme Court has held that “unfair prejudice” as to a defendant refers to the capacity of evidence “to lure the fact-finder into declaring guilt on a ground different from proof specific to the offense charged.” *Old Chief v. United States*, 519 U.S. 172, 180 (1997). The probative value of the evidence in this case is low. The ATSDR and the Government’s own witnesses agree that it doesn’t provide support for an opinion on causation. The ATSDR has acknowledged that even the medical screenings don’t provide a basis for a diagnosis of an asbestos-related disease.

On the other hand, the potential for confusion and prejudice is paramount. The Government’s expert witnesses will use the Screening Program to suggest that there is a possibility that environmental exposure to Libby tremolite in the past caused asbestos-related

disease in over 1,000 Libby residents and will then suggest to the jury that they can infer that post-1999 exposures will also lead to increased asbestos-related disease. Compounding matters further, the Screening Program includes many former Grace workers who were exposed in the 1940s and 1950s before Grace purchased the mine, or in the 1960s and 1970s before the installation of the wet mill. *See Peipins* at 1755. The exposures of these individuals are substantially higher than any alleged environmental exposures post-1999. And, even with respect to some of the environmental exposures, like to “piles of vermiculite,” it appears that most if not all of those exposures occurred prior to any time period relevant to the Indictment. To allow the jury to hear evidence of pleural abnormalities among a population that contains many workers subject to high pre-1976 occupational exposures and other exposures that in no way relate to exposures that might exist post-1999, and then to allow them to infer the results to exceedingly low post-1999 environmental exposures, is extremely prejudicial to the Defendants. For these reasons, the Screening Program should be excluded under Rule 403. *See Mukhtar*, 299 F.3d at 1063-64 (holding that 403 balancing can be used to counter-act the “aura of authority experts often exude, which can lead juries to give more weight to their testimony” than they deserve.). *Rogers v. Raymark Indus., Inc.* 922 F.2d 1426, 1430 (9th Cir. 1991) (evidence excluded because “the proffered testimony had the potential of confusing the jury because the asbestos exposures described in the testing were substantially different from the conditions of the exposures relevant to the case”).

V. THE SCREENING PROGRAM SHOULD BE EXCLUDED BECAUSE THE GOVERNMENT HAS FAILED TO PRODUCE ALL OF THE UNDERLYING DATA

The Court must exclude the ATSDR Screening Program on the ground that the Government has failed to provide discovery of the underlying x-rays and HRCTs that formed the basis for the conclusions reached by the ATSDR Screening Program. *See* letter from Mclean to

Mace, December 19, 2005, Exh. 12. Without the underlying x-rays and HRCTs, the Defendants are unable to test the findings of the ATSDR Screening Program and are powerless to evaluate the impact of and bias caused by methodological flaws. The failure to produce that evidence in a timely fashion requires exclusions of all evidence based upon the ATSDR Screening Program. As this Court has recognized, both Rule 16 and “[c]onsiderations of fairness and due process require that the Defendants not be forced to defend against a serious allegation of widespread health problems caused by their conduct without also having access to the data upon which the allegation is based.” 11/23/05 Order at 7 [Docket No. 236].

However, the Defendants recently discovered that some of the x-rays and HRCTs from the ATSDR Screening Program appears to reside in the files of the Government’s own witnesses – Drs. Black and Whitehouse. The Government and the Defendants are working on identifying and producing any x-rays and HRCTs in Dr. Whitehouse’s and Dr. Black’s possession, and Defendants reserve the right, at the very least, to supplement this motion based on the review of those records, and to seek an appropriate amount of time to evaluate the ATSDR data that, as of the date of this filing, has yet to be produced.

CONCLUSION

For these reasons, Defendants’ motion in limine should be granted and the Government should be precluded from introducing evidence relating to the ATSDR Screening Program.

DATED this 31st day of May, 2006.

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L.R. 5.2(b)**

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